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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,864	12/20/2001	Thomas Ried	14014.0319U2	8947

7590 09/17/2003

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EXAMINER

YU, MISOOK

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 09/17/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/937,864

Applicant(s)

RIED ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 July 2003 and 22 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2 and 7-25 is/are pending in the application.
- 4a) Of the above claim(s) 21-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,7-20,24 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 16.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4-22-2003 has been entered.

### ***Election/Restrictions***

Claims 21-23, directed to an invention that is independent or distinct from the invention originally claimed for the reason of record. Accordingly, claims 21-23 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Applicant argues that the steps of claims 21-23 are similar. However, the withdrawn claims 21-23 have different objectives and effects, i.e. the invention does not necessarily detect cancer or predict cancer outcome.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1, 2, and 7-25 are pending and claims 1, 2, and 7-20, 24, and 25 are examined on merits.

### ***Claim Rejections - 35 USC § 102***

The rejection of claims 1, 2, 7-15, 17 under 35 U.S.C. 102(b) as being anticipated by WO97/38313 (IDS A2) is **withdrawn** because applicant argument, that the enriching step of the prior art and instant invention is different applicant, is persuasive.

The rejection of claims 16, 18, and 20 under 35 U.S.C. 102(a) as being anticipated by Racila et al (IDS A26) is **withdrawn** because on reconsideration, applicant argument, i.e. the prior art teaches diagnosing cancer by detecting epithelial cells in peripheral blood, and instant invention is directed to method of detecting cancer cells by detecting cancer cells directly, is persuasive.

### **NEW GROUNDS OF REJECTION**

#### ***Claim Rejections - 35 USC § 102***

Claims 16, 18, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/02002 (a copy provided with ISR, and IDS A4).

The claims are interpreted as drawn to method of detecting cancer cells using antibody capable of binding to cancer marker for the purpose stated in the preamble of the claims, i.e. for determining status of a cancer, progression, and effectiveness of an anti-therapy. WO 96/02002 teaches detecting epithelial cancer cells using anti-E-cadherin and anti-alpha-catenin for determining status of a cancer, progression, and effectiveness of an anti-therapy. Note Examples at pages 30-49, Figs 1-3, claims 1-5, 7, and 8.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 7-15, 17, 19, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over either US Pat. 6,365,362 B1 (filing date Feb. 12, 1999) or Racila et al (IDS A26, cited in the previous Office action) for enriching step, and WO 97/38313 (IDS, and also cited in previous Office action) for detection step.

The claims are interpreted as drawn to method of detecting circulating cancerous epithelial cells by enriching said epithelial cells first using something binds to said epithelial cells, followed by detection of cancer cells using nucleic acid probes.

Either US Pat. 6,365,362 B1 or Racila et al teaches how to enrich circulating epithelial steps using cytokeratin screening or magnetic particles connected to a ligand capable of binding epithelial cells. Note Method section of Racila et al. Also note Example 1 (column 17-22), claims 1, 2, and 6 of US Pat. 6,365,362 B1.

WO97/38313 teaches all the reagents necessary to distinguish cancer cells from non-cancer cells using the hybridization pattern of nucleic acids (see page 21 to the first paragraph of page 26) and multiple probes (Example 7). The disclosed examples of probe associated with specific cancer and a genetic marker are PSMA, PSA, and centromeric regions of chromosomes 7, 8, 18 (page 21-22). Further, WO97/38313 teaches methods of determining status and progress of cancer patient, and monitoring efficacy of cancer treatment at page 3 lines 18-26, page 25, lines 19-26, examples 2, 7 and 11. Also note claims 1, 6, 7, and 15-17, 26, 29, and 31.

The combination of the three references fails to <sup>explicitly</sup> teach or suggest the claimed invention. However, various methods of distinguishing cancer cells from non-cancerous cells are known in the art to be used in with combination of enriching circulating

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epithelial cells and the enriching the circulating cells using the method claimed in the instant invention is also known in the art. US Pat. 6,365,362 teaches cancer metastasis involves shedding of epithelial cells in blood from the early state of cancer development (State 1) but the detection is difficult to detect because the quantity is too small although detection of early shedding is critical for prevention serious metastasis. See the background and Fig. 8. The methods of the instant claims can be viewed as a method drawn to combining two steps known in the art, i.e. an *In re Kerkhoven* analysis (*In re Kerkhoven*, 626, F.2s 846, 850, 205 USPQ 1069, 1072 (CCPA 1980)). The court held that it is obvious to combine two compositions, in order to form a third composition, when each of the two compositions is taught by the prior art to be useful for the same purpose. The idea of combining them flows logically from their having been individually taught in the prior art (MPEP 2144.06). Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the enriching step and a detection step known to be useful for detecting shedding of epithelial cells by tumors with reasonable expectation of success.

### ***Conclusion***

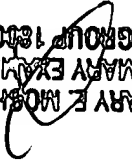
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
MARY E. MOSHER  
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Misook Yu

September 12, 2003